

REMARKS

This Response is submitted in reply to the non-final Office Action mailed on August 20, 2010. A Petition for a two month extension of time is submitted herewith this Response. The Commissioner is hereby authorized to charge \$490.00 for the Petition for a two month extension of time and any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00600 on the account statement.

Claims 1, 3, 6-9, 13-17 and 20 are pending in this application. Claims 2, 4, 5, 10-12 and 18-19 were previously canceled without prejudice or disclaimer. In the Office Action, Claims 1, 3, 6-9, 13-17 and 20 are rejected under 35 U.S.C. §112. Claims 1, 3, 6-9, 13-17 and 20 are rejected under 35 U.S.C. §103. For the reasons set forth below, Applicants respectfully submit that the rejections should be reconsidered and withdrawn.

In the Office Action, Claims 1, 3, 6-9, 13-17 and 20 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Specifically, the Patent Office states that “[a]t least one means one and more” and the specification discloses adding “proteinase and xylanase.” The Patent Office submits that there is no disclosure of adding more than one proteinase and more than one xylanase. See, Office Action, page 2, lines 1-10. Applicants respectfully disagree.

The specification clearly discusses that “[w]afer manufacture uses enzymes, preferably endo-proteinases (such as neutral bacterial proteinase from *Bacillus subtilis* or papain from *Carica papaya*) . . . and also xylanase (pentosanase).” See, specification (Substitute Specification), page 4, lines 4-12. The specification further discloses “a batter treated with proteases, such as endo-proteinases, or xylanases (pentosanases), or a combination of these types of enzymes.” See, specification, page 4, lines 4-12; page 10, lines 13-18. As such, the specification clearly refers to proteinases and xylanases, plural, and even discloses several different types of proteinases. Further, the skilled artisan would appreciate that, for example, “xylanase” is the name given to a class of enzymes which degrade the linear polysaccharide beta-1,4-xylan into xylose, thus breaking down hemicellulose, one of the major components of plant cell walls. See, e.g., Wikipedia, “xylanase.” Similarly, a “proteinase” (also termed peptidase or protease) breaks down proteins. A proteinase is any enzyme that conducts proteolysis, that is, begins protein catabolism by hydrolysis of the peptide bonds that link amino

acids together in the polypeptide chain forming the protein. See, e.g., Wikipedia, "protease." Accordingly, it is clear that neither a proteinase nor a xylanase is a singular compound, but rather are classes of enzymes that contain many different types of same.

As such, since the specification clearly discloses "endo-proteinases (such as neutral bacterial proteinase from *Bacillus subtilis* or papain from *Carica papaya*) . . . and also xylanase (pentosanase)," as well as "a batter treated with proteases, such as endo-proteinases, or xylanases (pentosanases), or a combination of these types of enzymes," see, specification, page 4, lines 4-12; page 10, lines 13-18, it is clear that the specification discloses "adding more than one proteinase and more than one xylanase," in contrast to the Patent Office's statement.

For at least the reasons set forth above, Applicants respectfully submit that Claims 1, 3, 6-9, 13-17 and 20 fully comply with the requirements under 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that the written description rejection of Claims 1, 3, 6-9, 13-17 and 20 be reconsidered and withdrawn.

In the Office Action, Claims 1, 3, 6-9, 13-17 and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2003/0072862 to Pruden et al. ("*Pruden*") in view of WO 02/39820 to Huang et al. ("*Huang*"). Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Independent Claims 1, 9, 14 and 15 recite, in part, wafers or wafer batters comprising at least one proteinase, at least one xylanase, sodium bicarbonate and a thermostable α -amylase present in an amount of 10 to 1000 units per gram of a final dough batter. Embodiments of the present invention are directed to flour-based food products comprising wafers formed from wafer batters including at least one proteinase, at least one xylanase, sodium bicarbonate and α -amylase that is used to manipulate certain textural attributes of the wafers. Using α -amylase in wafers induces two main effects which will affect the wafer textures. First, the enzyme will induce a decrease in the starch viscosity at the baking step, leading to a modification in the expansion and the size of gas bubbles. Second, the enzyme will modify the macromolecular structure of starch leading to a modification of the physical properties in the solid cell walls of the dried wafer. The wafers of the present invention also have a final humidity that is not greater than 6%.

Applicants have surprisingly found that the enzymatic cleavage of starch operated by the α -amylase increases the level of reducing sugars and so facilitates the browning reactions of the

wafer together with a positive impact on the flavor of the final products. Specifically, Applicants have found that the more α -amylase that is contained in the batter, the faster the browning of the wafer is obtained. Applicants have also found that there exists a relationship between the level of α -amylase incorporated into the batter and the hissing time during baking (*i.e.*, the time period corresponding to the audible noise produced by gas and steam release at the beginning of the baking phase). See, specification, page 9, line 18-page 10, line 2. Further, by varying the enzyme concentration of the present wafers (e.g., α -amylase, proteinase and xylanase), it is possible to produce a wide range of starch degradation profiles to obtain different wafer textures. In contrast, Applicants respectfully submit that *Pruden* and *Huang* fail to disclose each and every element of the present claims.

For example, *Pruden* and *Huang* fail to disclose or suggest wafers comprising a thermostable α -amylase present in an amount of 10 to 1000 units per gram of a final dough batter as required, in part, by independent Claims 1, 9, 14 and 16. Indeed, the Patent Office fails to even point to any disclosure in either *Pruden* and *Huang* that discloses same. For example, *Pruden* is entirely directed toward a bakery product having an extended shelf life. The product may include amylase, but only in an amount of about 0.21 to about 6 parts by total weight dough, or 0.01 to 1% by total weight of the dough. See, *Pruden*, Abstract; page 1, [0010]; page 5, Table II. This amount is less than the amount of α -amylase claimed in the present claims. The Patent Office even admits that *Pruden* fails to disclose a wafer having an enzyme in units. See, Office Action, page 4, lines 10-11. At no place in the disclosure does *Pruden* even suggest wafers comprising a thermostable α -amylase present in an amount of 10 to 1000 units per gram of a final dough batter as required, in part, by independent Claims 1, 9, 14 and 16.

The Patent Office asserts, however, that “[w]hile *Pruden* does not disclose the enzyme units, the concentration of enzyme disclosed in *Pruden* falls within the range of enzyme concentration disclosed in the instant specification.” See, Office Action, page 4, lines 10-12. The Patent Office further asserts that “[s]ince the enzyme in *Pruden* is the same enzyme as claimed and the amounts fall within the range disclosed, it is inherent the enzyme units are within the broad range claimed.” See, Office Action, page 4, lines 14-17. Applicants respectfully disagree. Applicants submit that the Patent Office has erroneously imported limitations from the specification into the claims with the statement that “*Pruden* falls within the range of enzyme concentration disclosed in the instant specification.” See, Office Action, page

4, lines 10-12. Indeed, the present claims do not recite the percentages cited in the specification by the Patent Office. Accordingly, Applicants submit that it is improper for the Patent Office to reject the present claims based on the disclosure in the specification.

Further, to satisfy the test for inherency, the Patent Office would be required to show that the enzyme amounts of *Pruden* are necessarily (i.e., always or automatically) within the amount of 10 to 1000 units per gram of a final dough batter. That condition simply is not met under the present circumstances. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See, MPEP 2112. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). The Patent Office has failed to demonstrate that the amylase of *Pruden*, in an amount of about 0.21 to about 6 parts by total weight dough, or 0.01 to 1% by total weight of the dough, falls within the claimed range of thermostable α -amylase.

As discussed in the specification, *Huang* is entirely directed to the use of high molecular weight starch hydrolysates or crystalline hydrate formers (such as maltose, isomaltose, trehalose, lactose and raffinose) in food products such as bakery product, where crispiness is desired in a high moisture environment. See, specification, page 4, line 26-page 5, line 2. See, also, *Huang*, Abstract. At no place in the disclosure does *Huang* even suggest wafers comprising a thermostable α -amylase present in an amount of 10 to 1000 units per gram of a final dough batter as required, in part, by independent Claims 1, 9, 14 and 16. Accordingly, Applicants respectfully submit that neither *Pruden* nor *Huang* disclose or suggest wafers comprising a thermostable α -amylase present in an amount of 10 to 1000 units per gram of a final dough batter as required, in part, by independent Claims 1, 9, 14 and 16.

Applicants also respectfully submit that the skilled artisan would have no reason to modify *Pruden* with *Huang* to arrive at the present claims because *Pruden* is directed products that have completely different objectives. Further, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there exists no reason for the skilled artisan to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). This certainly applies here, where *Pruden* is entirely directed to extending the shelf-life from 16 days to about 26 days of a dough-based bakery composition by combining dough with a shelf-like extending composition. As described in *Pruden*, the enzyme would degrade the damaged starch, which is enough to help extend shelf-life. However,

partial hydrolysis of a starch by an enzyme in a dough cannot be reached since the lower moisture environments of a dough result in a thermally denatured amylase before crystalline starch is available for further hydrolysis (e.g., gelatinization).

In contrast, the present invention is entirely directed the use of α -amylase in wafers and wafer batters to modify the textural properties of wafers through viscosity modification of the batter in the oven. The modification leads to new microstructures (e.g., pore sizes) that cannot be achieved for a given formulation in any other way. This feature is unique since starch needs to be gelatinized before it can be partially hydrolyzed by the enzyme. While the high temperature of an oven may be deleterious to the enzyme (resulting in inactivation), the overall kinetics (e.g., enzyme inactivation rate, gelatinization rate, hydrolysis rate) of the present batters allow for some native starch to be hydrolyzed by the α -amylase. Applicants submit that this would not have been obvious to the skilled artisan.

Moreover, the compositions and methods of the present claims result in unexpected synergistic effects that overcome the present obviousness rejection. "One way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of 'unexpected results,' i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). Applicants have surprisingly found that using α -amylase in wafers induces two main effects which will affect the wafer textures. First, the enzyme will induce a decrease in the starch viscosity at the baking step, leading to a modification in the expansion and the size of gas bubbles. Second, the enzyme will modify the macromolecular structure of starch leading to a modification of the physical properties in the solid cell walls of the dried wafer. The wafers of the present invention also have a final humidity that is not greater than 6%.

Applicants have also surprisingly found that the enzymatic cleavage of starch operated by the α -amylase increases the level of reducing sugars and so facilitates the browning reactions of the wafer together with a positive impact on the flavor of the final products. Specifically, Applicants have found that the more α -amylase that is contained in the batter, the faster the browning of the wafer is obtained. Applicants have also found that there exists a relationship between the level of α -amylase incorporated into the batter and the hissing time during baking (i.e., the time period corresponding to the audible noise produced by gas and steam release at the

beginning of the baking phase). See, specification, page 9, line 18-page 10, line 2. Further, by varying the enzyme concentration of the present wafers (e.g., α -amylase, proteinase and xylanase), it is possible to produce a wide range of starch degradation profiles to obtain different wafer textures. These results are clearly indicated by the test results detailed in the Examples in the present specification.

For example, as shown by Examples 1-5, it can be seen that different wafer textures can be obtained by producing a wide range of starch degradation profiles. This is achieved, at least in part, by using wafer batters that contain sodium bicarbonate and an enzyme blend including a proteinase, xylanase and α -amylase. See, e.g., Examples 1-5. Specifically, Example 4 demonstrates that using different amounts of α -amylase results in different sensory characteristics of the final wafer product including, for example, hardness, brittleness, crispness and textural properties. See, Example 4. Therefore, with the synergistic effect of wafers and wafer batters containing sodium bicarbonate and an enzyme blend including a proteinase, xylanase and α -amylase, Applicants have achieved a wide range of physical properties for wafers.

Applicants also respectfully submit that what the Patent Office has done is to rely on hindsight reconstruction of the claimed invention. Indeed, it is only with a hindsight reconstruction of Applicants' claimed invention that the Patent Office is able to even attempt to piece together the teachings of the prior art so that the claimed invention is allegedly rendered obvious. Instead, the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). One should not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. (Fed. Cir. 1988).

For at least the reasons discussed above, Applicants respectfully submit that Claims 1, 3, 5-9, 12-17 and 20 are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 3, 5-9, 12-17 and 20 under 35 U.S.C. §103(a) as being unpatentable over *Pruden* in view of *Huang* be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

K&L GATES LLP

BY 

Robert M. Barrett
Reg. No. 30,142
Customer No.: 29157
Phone No. 312-807-4204

Dated: January 18, 2011